IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES ATTACHED ON EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF DAUBERT MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF REBECCA M. RYDER, M.D.

Plaintiffs, Joyce Justus ("Ms. Justus") and Dee McBrayer and Timothy McBrayer ("Mr. and Mrs. McBrayer") (collectively "Plaintiffs"), hereby seek to exclude certain opinions and testimony proffered by Defendant Ethicon's ("Defendant") expert Rebecca M. Ryder, M.D. ("Dr. Ryder"). In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Ryder is a medical doctor board certified in obstetrics and gynecology with a subspecialty certification in pelvic floor medicine and reconstructive surgery. *See* Ex. B, Expert Report of Rebecca M. Ryder, M.D., MDL General Report – Prolift ("Ryder Expert Report") at 1; Ex. C, Curriculum Vitae of Rebecca M. Ryder, M.D. ("Ryder CV"). Plaintiffs do not challenge her qualifications as such. However, Dr. Ryder has proffered opinions in the following areas: (1) defective design of the Prolift; (2) degradation of polypropylene, specifically the Prolift, in a woman's body; (3) safety of the material properties of polypropylene mesh used in the Prolift product; and, (4) risk of infection. It is Plaintiffs' position that these opinions far exceed the

bounds of her qualifications and are founded on insufficient facts and unreliable methodology. *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (holding that the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue).

Dr. Ryder's experience in the field of obstetrics and gynecology, with a subspecialty certification in pelvic medicine and reconstructive surgery, does not render all of her opinions admissible. The admissibility of Dr. Ryder's unfounded opinions is contrary to law and presents serious risks of confusing the issues and misleading the jury in this case. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) ("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.'") (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 596 (1993)). Moreover, as this Court noted, "[j]ust because an expert may be 'qualified . . . by knowledge, skill, experience, training or education' does not necessarily mean that the opinion that the expert offers is 'the product of reliable principles and methods' or that the expert 'has reliably applied the principles and methods to the facts of this case.'" *Cisson v. C. R. Bard, Inc. (In re C. R. Bard, Inc.)*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013). Accordingly, Dr. Ryder should be prevented from offering testimony or opinions that exceed those permitted under the federal rules and *Daubert* and its progeny.

PRELIMINARY AND FACTUAL STATEMENT

A. Dr. Ryder's Educational Background

Dr. Ryder completed her medical degree at the University of North Carolina at Chapel Hill in 1989. Ex. C, Ryder CV. She then completed a residency program in Obstetrics and Gynecology at the same institution in 1993. *Id.* Dr. Ryder has not completed a residency program in either general surgery or urology or a Fellowship recognized by the Accreditation

Council for Graduate Medical Education in any area of medicine. Ex. D, Dr. Rebecca Ryder 3/21/16 Dep. Tr. ("Ryder Dep. Tr.") at 21:3-15; 20:20-24; 21:1-2. During her residency training in obstetrics and gynecology, Dr. Ryder had not heard of transvaginal mesh as a use of treatment for pelvic organ prolapse ("POP") or stress urinary incontinence ("SUI"). *Id.* at 27:9-13. Dr. Ryder received her subspecialty certification in female pelvic medicine and reconstructive surgery in 2013. Ex. D, Ryder Dep. Tr. at 21:16-19. She was "grandfathered" in and did not have to complete a Fellowship to receive her certification in this area. *Id.* at 21:20-23. Dr. Ryder obtained her subspecialty certification in 2013, Ex. C, Ryder CV, one year after Ethicon pulled Prolift off the market, Ex. D, Ryder Dep. Tr. at 130:19-21, and five years after Dr. Ryder last surgically implanted a Prolift device into a woman's body. *Id.* at 119:6-9.

Dr. Ryder has never taken graduate level classes in the areas of engineering, material sciences or polymer materials.[1] *Id.* at 24:17-21; 25:12-17. Moreover, she has never engaged in academic research that was the basis for a thesis in order to obtain any type of graduate degree in any area of study. *Id.* at 23:20-23.

B. Dr. Ryder's Lack of Research with Transvaginal Mesh

Dr. Ryder has never been a clinical trial manager or a clinical trial leader for a study using transvaginal mesh for treatment of SUI or POP. *Id.* at 28:15-19. Further, she has not published a peer reviewed article directly addressing the use of polypropylene as a transvaginal surgical treatment for SUI or POP. *Id.* at 28:10-14. Lastly, Dr. Ryder is not currently a peer reviewer for any scientific or medical journal. *Id.* at 27:19-21. Even during her time as a peer review, Dr. Ryder never reviewed an article dealing with transvaginal mesh. *Id.* at 28:7-9.

C. Dr. Ryder's Training on the Prolift Device

[1] As an undergraduate student pursuing a bachelor's degree in Public Health, she took a class that was titled either environmental engineering or environmental science. Ex. D, Ryder Dep. Tr. at 24:24; 25:1-11).

Dr. Ryder was trained on how to surgically implant the Prolift device for the treatment of POP on April 11, 2005, *id.* at 87:15-17, in Allentown, Pennsylvania by Vince Lucente, M.D. *id.* at 88:8-10, a paid consultant for Ethicon who personally took credit for getting the February 2007 ACOG Bulletin on POP replaced by the September 2007 ACOG Bulletin wherein the word "experimental" is no longer used in conjunction with Prolift and patients consent to surgery with an understanding of postoperative risks, complications and lack of long-term outcomes data, Ex. G, Email chain, ETH.MESH.00467706-ETH.MESH.00467709. During this one day training session, Ex. D, Ryder Dep. Tr. at 60:2-3, she *thinks* that she viewed a PowerPoint presentation and slides that presented the history of the TVM procedure, abstracts and initial experiences in centers in France and the U.S. *Id.* at 91:15-92:7. Other than this one day training, Dr. Ryder has no recollection of receiving any other Ethicon training on the Prolift device. *Id.* at 98:4-11.

D. Dr. Ryder's Use of Polypropylene and the Prolift Device in Patients

Over the course of 27 years, Dr. Ryder has performed over 1000 surgical procedures on women for repair of POP and/or SUI. Ex. B, Ryder Expert Report at 2. However, only 150 to 200 of those surgeries involved the use of polypropylene, Ex. D, Ryder Dep. Tr. at 134:8-13, the material used in most transvaginal mesh devices, including Prolift. Of those 150 to 200 surgeries, approximately 100 involved the use of the Prolift device for treatment of POP. Ex. B, Ryder Expert Report at 2. The last three to four years that Prolift was commercially available, she did not use it for the surgical treatment of POP, preferring Boston Scientific's Uphold device because it provided better apical support. Ex. D, Ryder Dep. Tr. at 117:18-118:3; 118:14-17. Thus, Dr. Ryder is proffering opinions on the safety of the material of a product she has not used in eight years. *Id.* at 119:6-9.

To her knowledge, Dr. Ryder approximately had a 10% complication rate out of those 100 Prolift cases. *Id.* at 116:11-19. However, she admits that some of her patients who experienced complications could have sought treatment with other physicians and, thus, she does not know the true complication rate. *Id.* at 117:2-9.

E. Dr. Ryder's Base of Knowledge on the: Design of the Prolift; Safety of the Gynecare Gynesmesh PS Mesh Material; Degradation of the Prolift Mesh Material in a Woman's Body; and, Risk of Infection from Prolift

1. Basis of Opinions

Dr. Ryder's opinions regarding safety and efficacy are based upon her review of the medical literature, her attendance at professional meetings, position papers by the societies, her personal experience with patients, and FDA reports. *Id.* at 105:17-106:2; 125:17-126:5. The opinions are based upon what she believes the facts to be regarding the Prolift device. *Id.* at 106:4-8. Also, Dr. Ryder is relying upon what she learned about the Prolift device from Dr. Lucente during her one day training session that occurred over 11 years ago in Allentown, PA. *Id.* at 107:4-9.

Except for the 10 to 20 articles she added herself, the remainder of the 382 articles that are listed in Ex. E, List of Materials Reviewed, Prolift General Report of Rebecca Ryder, M.D. ("Materials Reviewed") were provided to Dr. Ryder by Ethicon. *See* Ex. D, Ryder Dep. Tr. at 44:9-17; 44:23-45:4; 45:17-46:4.

In formulating her opinions, Dr. Ryder testified that her review of the articles identified in the table below were most relevant and important:

TABLE 1
Journal Articles (Study)
Altman (2011) Anterior Colporrhaphy versus Transvaginal Mesh for Pelvic Organ Prolapse. *NEJM* May 12, 2011 pgs 1826 – 1836
Beji et al (2003) The effect of pelvic floor training on sexual function of treated patients. *Int*

Urogynecol J Pelvic Floor Dysfunct 2003 Oct: 14(4):234-8
Berrocal (2004) Conceptual advances in the surgical management of genital prolapse. The TVM technique emergence. *J Gynecol Obstet Biol Rerpod* 2004; 33: 577-587
daSilveira (2014) Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. *Int Urogynecol J.* 09 September 2014 [Pop 184, 1 yr fu]
Dietz & Maher (2013) Pelvic organ prolapse and sexual function. *Int Urogynecol* (2013) 24:1853-1857
Feiner, B. (2008) Efficacy and safety of transvaginal mesh kits in the treatment of prolapsed of the vaginal apex: a systematic review. The Authors Journal compilation *BJOG an International Journal of Obstetrics and Gynecology.*
Halaska et al (2012) A multicenter randomized prospective controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. *Am J Obstet Gynecol* 2012; 207:301.e1-7
Handa et al (2004) Sexual function among women with urinary incontinence and pelvic organ prolapse. *Am J Obstet Gynecol* (2004) 191, 751-6
Handa et al (2007) Sexual function before and after sacrocolpopexy for pelvic organ prolapse, *Am. J. Obstet. Gynecol.* 197(6):el-629-e6
Iglesia, C., et al. (2010) Vaginal Mesh for Prolapse: A Randomized Controlled Trial *Obstet Gynecol.* 2010 Aug; 116(2 Pt 1):293-303.
Iglesia, C.B. (1997). The Use of Mesh in Gynecologic Surgery *Int Urogynecol J Pelvic Floor Dysfunct.* 1997;8(2):105-15
Jacquetin & Cosson (2009)[Pop, 2,078] Complications of vaginal mesh: our experience. *Int Urogynecol J* (2009) 20:893-896
Jacquetin, B. (2010) Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapsed: a 3-year prospective follow-up study. *Int. Urogynecol J* 21:1455-1462
Jacquetin, et al. (2006) (abstract 291) Prospective Clinical Assessment of the Trans Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse – One Year Results of 175 Patients
Jacquetin et al. (2013) Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5 year prospective follow up study. *Int Urogynecol J* 2009;20:S176-S7
Kahn, M.A., Stanton, S.L. (1997) Posterior colporrhaphy: its effects on bowel and sexual function, *Br. J. Obstet. Gynaecol. 104(1): 82-86*
Karram & Maher (2013) Surgery for posterior vaginal wall prolapse *Int Urogynecol J* (2013) 24: 1835-1841
Lowman et al (2008) Does the Prolift system cause dyspareunia? *Am. J. Obstet. Gynecol.) 199(6):707-712*
Maher et al (2004). Laparoscopic colposuspension or tension-free vaginal tape for recurrent stress urinary incontince and/or intrinsic sphincter deficiency-a randomised contolled trial. (*Neurourol Urodyn* 2004);23:433-434
Maher et al (2013) Cochrane Review Surgical management of pelvic organ prolapse in women
Maher et al (2016) Cochrance Review: Tranvaginal Mesh or grafts compared with native tissue repair for vaginal prolapse
Maher et al (2016) Summary Cochrane Review: Transvaginal Mesh or grafts compared

with native tissue repair for vaginal prolapse.
Nieminen, K. (2008) Symptom resolution and sexual function after anterior vaginal wall repair with or without polpyroplene mesh. *Int Urogynecol J* (2008) 19:1611-1616
Nieminen, K. (2010) Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. Sept 2010 *Amer J of Obstet & Gynecol*
Nicita (1998) A new operation for genitourinary prolapse *J Urology.* Vol 160 741-745, Sept 1998
Nilsson et al (2001) Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Stress Urinary Incontinence. *Int Urogynecol J* (2001) (Suppl 2):S5-S8.
Nilsson, C (2008) Eleven years prospective follow-up of the tension free vaginal tape procedure for treatment of stress urinary incontinence. *Int. Urogynecol J* (2008) 19: 1043-1047
Nilsson, C.(2013). Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int. Urogynecol J.* 2013;24(8):1265-9
Sokol et al (2012) One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. *Am J Obstet Gynecol* 2012; 206: 86.e1-9 (fup to Iglesia 2010)
Svabik et al (2014) Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial *Ultrasound Obstet Gynecol* 2014
Weber, A.M., et al (2000) Sexual function and vaginal anatomy in women before and after surgery for pelvic organ prolapse and urinary incontinence, *Am. J. Obstet. Gynecol.* 182(6):1610-1615
Withagen, M.I. (2011) Trocar-Guided Mesh Compared with Conventional Vaginal Repair in Recurrent Prolapse, A Randomized Controlled Trial. Vol. 117, No. 2, Part 1, *Obstetrics and Gynecol*
Wu, JM, et al. (2014) "Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery", *Obstet Gynecol,* 2014 col. 123(6) pp. 1201-6

See id. at 48:3-50:8.

Neither the above articles nor their underlying observational or experimental studies or meta-analysis reviews specifically or directly address the issues of: the material properties of the Prolift mesh, polymer science or degradation of polypropylene.

In sum, Dr. Ryder's opinions are not based upon any the following: educational background and training in material science, polymer science or engineering; academic research in material sciences or polymer sciences; personal testing of the Prolift material; or, clinical trials testing the Prolift material that Dr. Ryder managed, led or even participated in.

2. Dr. Ryder's Lack of Knowledge Regarding Design and Safety of the Material Used in the Prolift Device

Dr. Ryder does not consider herself to be an expert regarding the design of the Prolift. *Id.* at 106:18-20. She does not know the meaning of the term "design control" or "design requirement matrix." *Id.* at 108:11-17. Moreover, she does not possess knowledge about the internal steps Ethicon went through to get from the point where the idea of Prolift first occurred to the point where it was put on the market. *Id.* at 108:23-109:6. Indeed, her knowledge regarding the design of the Prolift device is solely limited to what she obtained during her April 11, 2005, training session from Dr. Lucente. *Id.* at 106:21-107:3. Dr. Ryder readily admitted that she has no knowledge about the criteria applied by Ethicon in deciding whether or not the Prolift should be put on the market in 2005. *Id.* at 103:24-104:3.

Specifically, when asked "who knows more about the risks and benefits of Prolift, [her] or Ethicon," Dr. Ryder testified "I know about the risks and benefits of using Prolift in my patients that are *clinically* applicable that I believe to be important to them, and for myself as the implanting surgeon." *Id.* at 105:8-15 (emphasis added). Dr. Ryder also testified that she neither knows who within Ethicon evaluated the safety of Prolift nor has she ever asked to see any information regarding whether Ethicon complied internally about the safety or efficacy of Prolift while it was on the market. *Id.* at 106:9-17.

Regarding Plaintiffs' own expert, Dr. Uwe Klinge, Dr. Ryder agrees that Dr. Klinge has a much higher degree of expertise in biomaterial sciences than she does. *Id.* at 111:4-12. Nevertheless, although Dr. Klinge opines that Prolift is not safe for use in POP, *see* Ex. F, Expert Report of Prof. Med. Dr. Uwe Klinge, these opinions do not alter Dr. Ryder's opinions on Prolift's safety, Ex. D, Ryder Dep. Tr. at 112:19-113:6. Indeed, the only thing that would alter

her opinion is if "women started coming down with cancer [or] if the clinical experience over time changes." *Id.* at 113:11-18.

Dr. Ryder does not know why Ethicon stopped marketing Prolift, and as part of her work as an expert, she never sought to find out why Ethicon stopped selling Prolift. *Id.* at 127:8-15.

Dr. Ryder testified that she does not know if lighter-weight mesh is considered in the urogynecology community literature to have safety advantages as against a heavier-weight mesh. *Id.* at 142:4-19. Dr. Ryder does not know whether mesh can contract in a woman's pelvis. *Id.* at 143:2-9. Additionally, Dr. Ryder would defer to doctors who have implanted far more transvaginal mesh than she has as to whether or not mesh extrusion into the vagina can cause infection, like it did in a case she reported to the FDA. *Id.* at 147:4-10.

However, even in light of her admissions regarding her lack of knowledge about the design and material properties of the Prolift, Dr. Ryder stated in her expert report that "[t]he Gynecare Gynemesh PS mesh used in Prolift is an appropriate, effective and safe material for use in this indication. Polypropylene mesh and sutures have been used an implant for decades. The pore size is sufficiently large to allow for proper tissue ingrowth, and has not presented increased risks of infection, particularly in relationship to other implants." Ex. B, Ryder Expert Report op. 2, at 21. Dr. Ryder testified that the basis for this opinion is her "review of the medical literature, the presentations at international meetings, national meetings, the physician statements by societies, and by clinical experience." Ex. D Ryder Dep. Tr. at 156:16-157:5.

ARGUMENT

I. Opinions Regarding Defective Design

Dr. Ryder's opinions regarding the defective design of Prolift must be excluded because (1) Dr. Ryder is not qualified to render such opinions and (2) the opinions have no reliable, scientific basis. In her expert report, Dr. Ryder opined the following:

> Gynecare Prolift is a safe and effective product that is supported by a substantial amount of clinical data, particularly when compared to alternative surgical approaches to treat prolapse. It is an appropriate treatment option for many women who suffer with this difficult and embarrassing condition. From my perspective as an experienced pelvic floor surgeon, and based on my review of the medical literature on Prolift and the use of transvaginal meshes to treat prolapse, Prolift's benefits far exceed its risks for many women **and it is not defectively designed**.

Ex. B, Ryder Expert Report op. 1, at 21 (emphasis added). For purposes of this Motion, Plaintiffs seek exclusion of Dr. Ryder's proffered opinion on defective design.

Dr. Ryder is not qualified to opine as to the defective design of Prolift. Indeed, Dr. Ryder herself even admitted as much.

> Q. Do you consider yourself to be an expert with regard to the design of the Prolift?
> A. Design, no.

Ex. D, Ryder Dep. Tr. at 106:18-20. Moreover, regarding the steps Ethicon took with the design and development of Prolift, Dr. Ryder testified that she is relying on the information presented to her by Dr. Lucente during her single day training session.

> Q. Do you have any information at all that you're relying on as an expert in this case about the steps that are taken, or were actually taken, with the design and the development of the Prolift by Ethicon?
> A. I have information that was presented to me at my Prolift training about the evolution of the TVM into the Prolift procedure.

Id. at 106:21-107:3. Likewise, Dr. Ryder testified that she does not know anything about the internal steps Ethicon took as a device manufacturer to develop Prolift.

Q. Do you know anything about the internal steps, anything at all that Ethicon took as a device manufacturer to develop the Prolift, meaning the internal steps that the company went through, to get from the point when somebody brought the idea to Ethicon about this particular product to the point that Ethicon was put on the market?
A. I don't believe so.

Id. at 108:23-109:6. Dr. Ryder also testified that she does not know what any of the following are: design control, design requirement matrix or FNEA. *Id.* at 108:11-19. Similarly, although she "may have run across" DDSA, she could not recall what it means. *Id.* at 108:20-22. These are all common terms that an expert opining to a product's defectiveness should, and would, know. Moreover, Dr. Ryder's CV shows that she: has never participated in development of any pelvic mesh device; has not authored a single peer-reviewed article on using polypropylene as a transvaginal surgical treatment for SUI or POP, let alone an article on the design, safety or efficacy of pelvic mesh products; and, has never managed, led or even participated in a clinical trial regarding the design, safety or efficacy of pelvic mesh products. *See* Ex. C, Ryder CV. Dr. Ryder also testified to as much in her deposition. *See* Ex. D, Ryder Dep. Tr. at 28:7-19.

In addition to Dr. Ryder being unqualified to opine to defective design, her opinions are also unreliable. Not only is Dr. Ryder's expert report wholly devoid of how she reached the conclusion that Prolift is not defectively designed, but it also contains no mention of the scientific methods, controls and veracity of the analysis she employed in reaching her opinion. Dr. Ryder did not even indicate or cite other peer-reviewed studies or methodologies on which she relied in forming her opinion. In other words, Dr. Ryder's opinion is not based on any methodology or scientific support, let alone reliable methodology. As such, this opinion must be excluded as unreliable. *See Foster v. Legal Sea Foods, Inc.*, No. CCB-03-2512, 2008 U.S. Dist. LEXIS 57117, at *30 (D. Md. July 25, 2008) ("A court will not credit an expert witness who

'testifie[s] to no customs of the trade, refer[s] to no literature in the field, and [does] not identify [relevant principles],' but merely [gives] 'his own subjective opinion.'") (alteration in original) (quoting *Freeman v. Case Corp.*, 118 F.3d 1011, 1016 (4th Cir. 1997).

Despite these admissions and Dr. Ryder's obvious lack of relevant education, background, training and experience, Defendants are nevertheless attempting to "slip in" an expert opinion that is unreliable and one that Dr. Ryder is not qualified to give. Dr. Ryder's opinions on defective design amount to nothing more than baseless assumptions, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent. *See Brown v. Auto-Owners Ins. Co.,* No. 96-2613, 1997 U.S. App. LEXIS 23559, at *3 (4th Cir. Sept. 8, 1997) ("[T]he expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation.").

II. Opinions Regarding Polypropylene Mesh Material, Mesh Pore Size, And Risk of Infection

Dr. Ryder's opinions regarding the use of polypropylene material, mesh pore size, and risk of infection must be excluded because (1) Dr. Ryder is not qualified to render such opinions; (2) the opinions have no reliable, scientific basis; and, (3) the opinions violate Fed. R. Civ. P. 26(a)(2)(B)(i). In her expert report, Dr. Ryder opined the following:

> The Gynecare Gynemesh PS mesh used in Prolift is an appropriate, effective and safe material for use in this indication. Polypropylene mesh and sutures have been used an implant for decades. The pore size is sufficiently large to allow for proper tissue ingrowth, and has not presented increased risks of infection, particularly in relation to other implants.

Ex. B, Ryder Expert Report op. 2, at 21. For purposes of this Motion, Plaintiffs seek exclusion of opinion 2 in its entirety.

Dr. Ryder is unqualified to render opinions regarding the mesh material's appropriateness, effectiveness, and safety. Dr. Ryder is also unqualified to opine that "[t]he pore

size is sufficiently large to allow for proper tissue ingrowth, and has not presented increased risks of infection." Dr. Ryder does not have any experience in material science and has never analyzed, tested or studied polypropylene mesh, Ex. D, Ryder Dep. Tr. at 24:17-21; 25:12-17; 28:10-19, or apparently reviewed literature on the subject, yet she arbitrarily offers opinions regarding the properties of polypropylene used in Ethicon mesh products. Indeed, Dr. Ryder testified that she neither knows who within Ethicon evaluated the safety of Prolift nor has she ever asked to see any information regarding whether Ethicon complied internally about the safety or efficacy of Prolift while it was on the market. *Id.* at 106:9-17. Additionally, when asked if she would defer to doctors who have implanted far more transvaginal mesh than she has as to whether or not mesh extrusion into the vagina can cause infection, like it did in the case she reported to the FDA, Dr. Ryder answered "[p]ossibly." *Id.* at 147:4-10.

Even if this Court determines that Dr. Ryder is qualified, the opinions should be excluded as unreliable. Dr. Ryder's report contains no methodology or citation to peer-reviewed articles for her conclusions regarding pore size and risk of infection. Moreover, the report contains no evidence or mention of Dr. Ryder performing any analysis or comparison of implants to reach the conclusion that "particularly in relation to other implants," Prolift's pore size "has not presented increased risks of infection." Since these opinions are unverifiable, are without scientific basis, and amount to unsupported speculation, they should be excluded as unreliable.

These opinions should be excluded under Fed. R. Civ. P. 26(a)(2)(B)(i), which requires export reports contain "a complete statement of all opinions the witness will express *and the basis and reasons for them*[.]" (Emphasis added). Contrary to the explicit terms of Rule 26, Dr. Ryder provides no basis and reasons in her report for her opinion that the "mesh used in Prolift is an appropriate, effective and safe material for use in this indication." Similarly, Dr. Ryder's

expert report is devoid of the basis and reasons for her opinion that "[t]he pore size is sufficiently large to allow for proper tissue ingrowth, and has not presented increased risks of infection, particularly in relation to other implants." Thus, these opinions should be excluded.

Put simply, Dr. Ryder does not have the requisite education, knowledge, training or experience to proffer these opinions, nor has she utilized *any* method – let alone a reliable method – to reach these conclusions.

III. Opinions Regarding Mesh Degradation

Dr. Ryder's opinions regarding mesh degradation must be excluded because (1) Dr. Ryder is not qualified to render such opinions; (2) the opinions have no reliable, scientific basis; (3) the opinions amount to non-expert lawyer arguments; and, (4) the opinions are irrelevant to the issues and scope of this case. In her expert report, Dr. Ryder opined the following:

> The body of clinical data for Prolift (and TVT, for that matter) does not support the conclusion that PROLENE® Soft mesh degrades in the body in any manner that has a clinical impact on patients. If it did degrade in a clinically significant way, surgeons would see far lower levels of durability in their Prolift repairs, and that is certainly not something that I have seen in my practice over many years. Nor would it make sense given that PROLENE® sutures have continued to be used in countless surgical applications for decades, including cardiac surgery.

Ex. B, Ryder Expert Report op. 3, at 21-22. For purposes of this Motion, Plaintiffs seek exclusion of opinion 3 in its entirety.

1. Qualification

Dr. Ryder is not qualified to render these opinions. Dr. Ryder is a board certified OB/GYN with a private practice focused on female urology and pelvic floor medicine. Ex. C, Ryder CV. She does not hold an undergraduate degree, nor has she even taken any graduate level courses, that provide her with the educational background to opine as to the degradation and material properties of polypropylene. Ex. D, Ryder Dep. Tr. at 24:17-21; 25:12-17. Further,

Dr. Ryder does not have any specialized training specifically related to polypropylene or the scientific, chemical or structural make-up of the Prolift device. Ex. C, Ryder CV. The extent of any relevant experience to this opinion appears only to be her clinical experience implanting Prolift devices and selective review of medical literature. However, rather than explanting or analysis and testing for degradation, her personal experience is limited to implanting Prolift. *Id.* Moreover, the articles that Dr. Ryder testified she most relied on in formulating her opinions do not specifically pertain to the scientific properties of polypropylene mesh. *See supra* Table 1 and accompanying text. Not only do the articles themselves not pertain to the properties of polypropylene, but even their underlying observational or experimental studies or meta-analysis reviews do not directly address the issues of Prolift's material properties or polymer science. *Id.* Despite her admitted lack of education, experience, training and knowledge about material and polymer sciences, Dr. Ryder attempts to opine on the mechanical changes that polypropylene may undergo. These opinions exceed her qualifications and, therefore, should be excluded.

2. Reliability

Regarding the basis for her opinions, unequivocally absent from Dr. Ryder's expert report, CV, and deposition testimony is any evidence that she has ever done any of the following: (1) tested polypropylene mesh to see if it degrades; (2) sought out and/or reviewed any additional information from Ethicon regarding the chemical makeup of polypropylene mesh; or (3) performed independent studies related to polypropylene degradation. Moreover, the expert report provides no scientific basis or methodology supporting her opinion, and the opinion cites none.

The fatal flaw in Dr. Ryder's opinions is that they appear to be premised solely on her *speculative assumption* that because polypropylene sutures can be used as permanent sutures,

and because such sutures are still able to be found many years after implant, absolutely no mechanical changes in any form are possible.

However, although Dr. Ryder confirms that she reviewed literature and documents provided by Ethicon, she did not ask Ethicon to provide her with all of the information that they have concerning degradation. Ex. D, Ryder Dep. Tr. at 132:6-11. Under *Daubert,* a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation." *Doe v. Ortho-Clinical Diagnostics, Inc.,* 440 F. Supp. 2d 465, 473-74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method). Most concerning is Dr. Ryder's assertion that there is *nothing* she could learn about the material used in the Ethicon's TVT or TVT-O products, or that she could see in the medical literature about polypropylene degradation, that would change her opinion. Ex. D, Ryder Dep. Tr. at 141:7-142:3. Simply because the selective literature provided by Ethicon does not address degradation and she chooses to presumptively disregard any literature contrary to her opinion that she has seen, or could see in the future, does not allow Dr. Ryder to testify in an expert capacity to her inference that degradation is not possible.

In support of her opinion, Dr. Ryder makes the sweeping conclusion that "surgeons would see far lower levels of durability in their Prolift repairs" if the material really did degrade. Ex. B, Ryder Expert Report op. 3 at 21. However, Dr. Ryder provides no basis, methodology or scientific material to support this conclusion. Although Dr. Ryder attempts to support this unfounded conclusion with personal experience, *id.*, nothing in her export report, CV or testimony establishes that she has any experience with Prolift repairs, explanting Prolift devices

or material degradation, let alone the requisite experience that renders an otherwise unsupported opinion scientifically reliable. In other words, Dr. Ryder makes a sweeping statement without any scientific methodology or support and then cites personal experience – mind you, experience that is not otherwise mentioned in her report – as conclusive proof of her own opinion. This is the epitome of an *ipse dixit* opinion.

Dr. Ryder has admittedly not used any scientific or medical methodology to come to her conclusions, and expert speculation such as this should necessarily be excluded. *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.").

3. Non-expert Arguments

Rather than opine, Dr. Ryder simply makes arguments that Defendants' lawyers can make at trial. In support of her opinion that the Prolift mesh does not degrade, Dr. Ryder argues that "[i]f it did degrade in a clinically significant way, surgeons would see far lower levels of durability in their Prolift repairs, . . . [n]or would it make sense given that PROLENE® sutures have continued to be used in countless surgical applications for decades, including cardiac surgery." Ex. B, Ryder Expert Report op. 3 at 21-22. Put another way, Dr. Ryder is stating a simple logical inference: that if the Prolift mesh material really degraded as plaintiffs contend, then PROLENE® material would have no continued medical application whatsoever. *See Cisson*, 948 F. Supp. 2d at 644 ("Simply pointing out inconsistencies does not require any 'scientific, technical, or other specialized knowledge.'") (quoting Fed. R. Evid. 702). Even ignoring for the moment that Dr. Ryder provides no basis or methodology comparing the degradation characteristics of PROLENE® sutures and the Prolift device, this inference is

nothing more than a non-expert lawyer argument best suited for trial. As such, this opinion is not expert testimony and should be excluded. *Daubert*, 509 U.S. at 590 ("[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method.").

4. Relevance

To the extent that Dr. Ryder's opinions rely on the body of clinical data for TVT, the opinion should be excluded as irrelevant. At issue here is Prolift and POP, not TVT. However, Dr. Ryder's opinion begins with "[t]he body of clinical data for Prolift (and TVT, for that matter) does not support the conclusion that PROLENE® Soft mesh degrades." Ex. B, Ryder Expert Report op. 3 at 21. Since this is a Prolift case, Dr. Ryder's opinions should not be based on the general and unspecified clinical body of TVT.

IV. Legal Conclusion

In her report, Dr. Ryder stated that "[u]ltimately, the Prolift brochures appropriately fulfill the limited purpose of a patient brochure and are not false or misleading." *Id.* at 16. To the extent that this is a legal conclusion, it should be excluded. *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").

CONCLUSION

For the reasons above, this Court should grant Plaintiffs' Daubert Motion to Exclude Certain Opinions and Testimony of Dr. Rebecca M. Ryder, M.D.

This 21st day of April, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

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